Approved 04/19/18
Last Date 04/10/18

University Hospitals™

To Ohio Department of Health, Attn: Wanda Iacovetta
Phone
Fax 614-564-2416

From
Phone UH Cleveland Medical Center
Fax
216-201-5390

Date
April 10, 2018

re

cc

Pages
11

Message
RE: UH Cleveland Medical Center, CCN: 360137, Survey: March 14, 2018, Plan of Correction

# Fax

**University Hospitals Fertility Center**
University Hospitals Ahuja Medical Center
Kathy Risman Pavilion
1000 Auburn Drive, Suite 310
Beachwood, OH 44122
Phone: 216-285-5028
Fax: 216-201-5390

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**University Hospitals Fertility Center**
Kathleen J. Sanniti
Director
1000 Auburn Drive
Kathy Risman Pavilion, Suite 310
Beachwood, OH 44122
(216) 844-1335

April 10, 2018

(Via email: ChicagoNLTCPOC@CMS.hhs.gov)
Centers for Medicare and Medicaid Services
Non-Long-Term Care Certification and Enforcement Branch
233 North Michigan Ave., Suite 600
Chicago, Illinois 60601
Attention: Pam Para, Nurse Consultant

(Via Fax: (614) 564-2416)
Ohio Department of Health
Office of Health Assurance and Licensing
Bureau of Survey and Certification
245 North High Street, 4th Floor
Columbus, Ohio 43215
Attention: Wanda Iacovetta

Re: UH Cleveland Medical Center
CCN: 360137
Survey: March 14, 2018
Plan of Correction

Dear Ms. Para and Ms. Iacovetta:

Enclosed please find the UH Cleveland Medical Center's plan of correction (POC) related to the above referenced survey. If you have any questions regarding the attached plan of correction, please contact me at (216) 844-1335 or Kathleen.Sanniti@UHhospitals.org.

Sincerely,

Kathleen J. Sanniti
Director
University Hospitals Fertility Center

Encl.
cc: James Liu, MD, Medical Director

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Last Date 04/10/18





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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| UH CLEVELAND MEDICAL CENTER | 11100 EUCLID AVENUE CLEVELAND, OH 44106 |

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| A 000 | INITIAL COMMENTS<br><br>Substantial Allegation Survey OH00096689<br><br>An entrance conference was conducted with administrative staff on 03/12/18 at 9:43 AM, and an exit conference was completed with the administrative staff on 03/14/18 at 11:45 A.M.<br><br>The following deficiencies are based upon the substantial allegation survey OH00096689 completed on 03/14/18. UH Cleveland Medical Center is not in compliance with the requirements 42 CFR Part 482 for Acute Care Hospital and the following deficiencies are cited. | A 000 | | April 10, 2018 |
| A 700 | PHYSICAL ENVIRONMENT<br>CFR(s): 482.41<br><br>The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community<br><br>This CONDITION is not met as evidenced by:<br>Based on staff interviews, observations and record reviews, it was determined the facility failed to ensure one liquid nitrogen storage container LN2 Tank (Container #1) used for egg and embryo storage was inspected and maintained (A0724) This affected 930 patients and involved a sum total of 2,751 eggs and embryos. | A 700 | A 724<br><br>Facility Position: This Plan of Correction is being submitted in accordance with a applicable law. The reviewer of this citation should note the following: UH Cleveland Medical Center is committed to providing quality services and has policies and procedures in place designed to ensure that its equipment is maintained to ensure acceptable levels of safety and quality. We immediately commenced to take actions upon learning of the problem with our fertility center. A very significant amount of activity took place from March 4, 2018 to the present. However, please accept April 10, 2018 as the date upon which all of these steps had been finalized and completed. | April 10, 2018 |
| A 724 | FACILITIES, SUPPLIES, EQUIPMENT MAINTENANCE<br>CFR(s): 482.41(c)(2)<br><br>Facilities, supplies, and equipment must be maintained to ensure an acceptable level of | A 724 | | April 10, 2018 |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: Kathleen J. Sanniti, Director — (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| A 724 | Continued From page 1<br>safety and quality.<br>This STANDARD is not met as evidenced by<br>Based on staff interviews, observations and record reviews, the facility failed to ensure one liquid nitrogen storage container LN2 Tank (Container #1) used for egg and embryo storage was inspected and maintained. This affected 930 patients and involved a sum total of 2,751 eggs and embryos.<br><br>Findings include:<br><br>1. Observation of the fertility clinic with Staff A on 03/12/18 between 3:58 PM and 4:32 PM revealed a liquid nitrogen storage container (Container #2) in the invitro laboratory area (Cryo room) which was being used to store eggs and embryos. Staff A stated this was a loaner tank which was put into use after the other liquid nitrogen storage container (Container #1) malfunctioned on 03/03/18 and was discovered on 03/04/18. Container #1 was observed beside Container #2 and was not currently in use to store eggs and embryos. Staff A also identified an additional smaller liquid nitrogen storage container (Container #3) that was in use to hold eggs and embryos which had not been transferred into the larger storage tank. Staff A stated after the storage container (Container #1) malfunctioned all the eggs and embryos were moved from Container #1 and placed into the loaner container (Container #2).<br><br>Containers #1, #2, the andrology container (for sperm storage) and the holding container were all observed with an electronic alarm device on the outside of the containers.<br><br>Staff A stated storage Containers #1 and #2 were | A 724 | A 700<br>A 724 (cont.)<br><br>There were a number of statements in this Statement of Deficiencies that could benefit from additional clarity. In the interest of brevity, we are limiting such clarifications to the following:<br><br>1. Container #1 had both a local alarm and a remote alarm (the remote alarm had been turned off at the time of the March 4 incident). These two separate alarms were set with different parameters, and thus at times an alarm condition for one alarm would not be an alarm condition for the other alarm. The January 2018 local alarm may not have triggered the remote alarm.<br><br>2. Through January 2018, Staff C was receiving communications indicating the remote notification system was working.<br><br>3. While the temperature of Container #1 is documented once per day, the temperature of Container #1 was monitored constantly by two temperature sensors in the container.<br><br>4. The first high temperature local alarm did not activate until 5:06 p.m. on March 3, 2018 at minus 156 degrees Celsius. | |

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| A 724 | Continued From page 2<br>each equipped with two sensors (one placed higher and one placed lower) inside the container which monitored temperatures inside the unit. Staff A stated in the event the alarm tripped, an audible alarm would sound on the container and the alarm would also be electronically submitted to a remote monitoring company in an offsite location, and the monitoring company would then notify the designated facility contact person via a robocall or email of the triggered alarm.<br><br>Staff A confirmed the liquid nitrogen level should be between 10-23 inches inside the storage container to maintain proper internal temperature and the local and remote alarms would sound if the temperature rose greater than -160 degrees Celsius (C).<br><br>2. On 03/13/18 between 4:37 PM and 5:30 PM, an interview was conducted with Staff C regarding the malfunctioning liquid nitrogen storage container (#1). Staff C stated the container had been used to store eggs and embryos until after a temperature malfunction occurred inside the container and the manual fill technique continued to be practiced until this same container malfunctioned due to increased internal temperatures on 03/03/18 and 03/04/18.<br><br>Staff C stated in January 2018 he/she was physically present in the facility when the local alarm sounded on Container #1. The alarm was due to a malfunctioning autofill sensor for the nitrogen level inside the container. Staff C stated the manufacturer was notified and staff were instructed to manually fill the container with liquid nitrogen due to the malfunctioning sensor.<br><br>Staff C stated he/she was not notified of the | A 724 | A 700<br>A 724 (cont.)<br><br>5. While the manufacturer of Container #1 provided recommended maintenance, there were no recommendations regarding the frequency of such maintenance. Following March 4, 2018, when asked to provide recommended frequencies, the manufacturer declined to do so.<br><br>**Plan of Correction:**<br><br>1. Container #1 was permanently removed from service on March 4, 2018.<br><br>2. All eggs and embryos were removed from Container #1 on March 4, 2018 and placed in Container #2.<br><br>3. All liquid nitrogen storage tanks now have a remote alarm notification system with an identified 3-tiered chain of persons receiving notification, totaling 5 people.<br><br>4. We have implemented a new policy and procedure to perform the checks and preventative maintenance in accordance with manufacturer's recommendations. While the manufacturer does not specify frequency, the policy and procedure we have implemented contains required frequencies for each maintenance step and test. Such maintenance and testing is documented as it occurs. Lab staff have been in-serviced on this policy and procedure by the lab director. | |

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| A 724 | Continued From page 3<br>electronically submitted alarm by the remote outside service company for the malfunction of Container #1's autofill sensor in January 2018, or when the temperatures increased to an unacceptable level inside Container #1 on 03/03/18. Staff C denied being present in the facility when the malfunction occurred inside Container #1 in March 2018. Staff C stated he/she should have been notified for these two events due to being the only designated contact person for those alarms.<br><br>Staff C denied any of the facility staff had contacted the outside remote monitoring company to question why the designated contact person did not receive the alarm in January 2018. There was no documented evidence provided by hospital staff of investigation as to why the designated contact person failed to receive notification of the automatic alarm in January 2018 when the autofill sensor alarm failed, and prior to the malfunction of the container related to increased temperatures inside the tank on 03/03/18.<br><br>Staff C stated on 03/04/18 he/she was not present in the facility when Staff E arrived and discovered a high unacceptable temperature of -37 degrees Celsius on the outside display panel of Container #1, which revealed the internal tank temperature. Staff C stated acceptable temperature inside the liquid nitrogen container should have remained between -160 degree Celsius (C.) and -180 degrees Celsius. Staff C stated -140 C is considered a safe temperature but -150 C and below is the desired temperature. Staff C stated "If alarm sounds and somebody responds, I would say they would have a couple hours to respond and the upper alarm tells the | A 724 | A 700<br>A 724 (cont.)<br><br>5. We have purchased 4 new liquid nitrogen tanks for egg and embryo storage. All 4 tanks are operational and are being monitored and maintained in accordance with the new policy noted above. Lab staff have been in-serviced on the use of these new tanks by the lab director.<br><br>6. We have implemented a new policy and procedure specific to our new remote monitoring technology. Lab staff were in-serviced on this new remote monitoring technology on March 22, 2018.<br><br>7. Embryology laboratory staff were inserviced on the chain of command on March 16, 2018.<br><br>8. The Lab Director or designee will conduct weekly audits of compliance with both policies described above for four weeks, and then monthly.<br><br>9. The MacDonald Quality Council will be receiving the results of these audits and taking any necessary action. | |

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| A 724 | Continued From page 4<br>levels have exceeded temperatures."<br><br>Staff C stated he/she was contacted on 03/04/18 by Staff F and Staff B of the unacceptable temperature. Staff C confirmed he/she again did not receive notification from the remote outside monitoring company of the alarm and stated he/she should have been notified of the alarm due to being the sole designated contact person.<br><br>Staff C stated the remote alarms for the liquid nitrogen containers were tested last March or April 2017; however, as of 03/14/18 the facility failed to provide documented evidence of this test.<br><br>Staff C stated he/she was onsite nine days a month and in other states the rest of the month.<br><br>3. On 03/12/18 at 1:30 PM, Staff L confirmed after the malfunction on 03/03/18, the facility staff contacted the outside remote monitoring company to investigate why the designated contact person was not notified about the unacceptable high temperature level inside Container #1 on 03/03/18. Staff L stated the alarm was received by the remote monitoring company, however, the alarm was not transmitted to the facility's sole designated contact person.<br><br>4. On 03/13/18 between 11:40 PM and 12:10 PM an interview was conducted with Staff E, who discovered the local audible alarm and increased unacceptable temperature inside the nitrogen storage Container #1 the morning of 03/04/18.<br><br>Staff E stated the following: He/she was the first person to arrive on 03/03/18 and 03/04/18. He/she arrived to the fertility lab on 03/04/18 | A 724 | | |

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| A 724 | Continued From page 5<br>around 7:12 AM, went into the Cryo room (Used to house Container #1) at approximately 7:20 AM and observed an audible local alarm sounding on Container #1 and an internal temperature reading of -32 degrees C. Staff E shut off the audible alarm and notified Staff F by phone of the alarm and increased temperature. Staff B (physician) was informed as he/she was onsite who then notified Staff C (designated contact person) by phone. Staff E stated on the previous day on 03/03/18, he/she went into the Cryo room and observed the temperature prior to leaving around 1:20 PM, and stated the temperature reading was appropriate and denied hearing an audible alarm.<br><br>Review of the temperature logs revealed two internal temperature sensors (Sensor A and Sensor B). The temperature began rising inside Container #1 on 03/03/18 beginning at 2:00 PM. The internal temperature rose to -32 degrees C on Sensor A and -34 degrees C on Sensor B. The internal undesired elevated temperature rise continued until 03/04/18 at 3:00 PM at which time Sensors A and B were -185 degrees Celsius. The liquid nitrogen level inside the container was 13 inches at 2:00 PM on 03/03/18 when Sensor B was at -160 degrees C. The level dropped to 1 inch on 03/04/18 at 2:00 PM when the temperature inside the tank was -100 degrees C. on both Sensors A and B. Staff E confirmed prior to the malfunction of Container #1 on 03/03/18 and 03/04/18, the temperature readings were only recorded upon arrival to the facility in the morning and did not list a time of the recordings.<br><br>6. On 03/13/18 between 12:11 PM and 12:54 PM Staff F stated Staff E sent a text picture to Staff F on 03/04/18 after 7:30 AM. Staff F stated the text picture was a temperature reading of -37 degrees | A 724 | | |

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| A 724 | Continued From page 6<br>C. on the digital control screen on top of Container #1. Staff F stated he/she arrived at 7:57 AM and confirmed the temperature reading on the digital gauge was too high. Staff F stated staff were trained to check an automatic digital screen on the outside of the nitrogen storage container which contained information for the temperature and liquid nitrogen fill level inside the storage container. Staff F also stated staff were to inspect the inside of the container for vapors by opening the top of the container. Staff F stated after receiving the text picture from Staff E on 03/04/18, upon arrival on that same date, there were no vapors present when the Container #1 was opened for inspection. Staff F stated the presence of vapors would indicate the presence of liquid nitrogen inside the storage container.<br><br>6. On 03/13/18 a review was conducted of the manufacturer's for use manual (Container 1). This manual contained the following:<br><br>"Prepare a contact list. Have at least 3 people on your contact list with Home, Cell and Pager Number. Review the list regularly for accuracy and changes."<br><br>"Recommended Best Practices. Secondary or backup alarm. It is strongly recommended to have, at a minimum, an independent temperature alarm for each LN2 freezer."<br><br>"Keep a daily log. Track temperatures daily. Record fill intervals and amount of LN2 filled into vessel (manual or pour-fill freezer or dewar). This information should be documented daily and reviewed monthly to foresee and prevent future problems such as temperature fluctuations and varying liquid levels." | A 724 | | |

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| A 724 | Continued From page 7<br><br>"Remote Alarm Connection to your Delta Room, Facility Monitoring Station or Remote Auto Dialer Q. Why should use my remote alarm feature or connection?<br>A. If an alarm occurs after hours, on a weekend or holiday the remote alarm connection will alert you to a problem and let you address it quickly."<br><br>"Check unit daily to ensure proper operation and safety of the stored samples. For the V series units (type used in facility), it is essential to lift the lid each day and check for vapor and signs of proper freezing."<br><br>"Cleaning and Maintenance. System Check<br>1. Test all alarm functions for proper operation.<br>2. Check any connected Remote Alarms or Automatic Dialing systems to ensure proper operation. See page 26 (of manual) for detailed instructions on how to manually cause a HIGH ALARM or LOW ALARM to test the remote alarm contacts.<br>3. Check for leaks at all connection points of the liquid nitrogen lines.<br>4. Be sure that all electrical wires are free of damage and plugs are firmly in place."<br><br>Until the malfunction of Container #1 was discovered on 03/04/18 by staff physically present in the room, the monitoring logs failed to indicate the amount of liquid in the storage tank or the presence/absence of vapors. Staff began logging observation of vapors and liquid nitrogen levels on 03/06/18.<br><br>There was no documented evidence of cleaning or inspection of Container #1 which included calibrating and testing of HIGH and LOW alarms, | A 724 | | |

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| A 724 | Continued From page 8<br>checking for leaks at all connection points of liquid nitrogen lines, or of the electrical wires to ensure they remained free of damage and plugs were firmly in place.<br><br>It was confirmed through staff interviews (Staff A, B, C, and H) prior to 03/03/18, there was only one sole designated contact person to receive notification of the remote electronic offsite alarm in the event of liquid nitrogen storage tank malfunction instead of three contacts recommended by the manufacturer's instructions.<br><br>7. During an interview with Staff H on 03/14/18 at 10:51 AM, Staff H verified there was no policy for notification of a designated person in relation to remote alarms for equipment (including nitrogen tank storage containers). Staff H stated the autofill issue on Container #1 was on or around 02/01/18 and confirmed the sole designated contact person (Staff C) did not receive notification of the remote alarm.<br><br>8. On 03/14/18 between 8:45 AM and 9:15 AM, Staff D, F, J, and L were made aware of the aforementioned concerns and no further information was provided at that time. | A 724 | | |